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APPLICATION NUMBER: ***60/689,147***
FILING DATE: ***June 10, 2005***

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. _____

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
GIL	NAOR	Ramat Hasharon, ISRAEL

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max):

Permanent Cerebral Embolic Protection Device

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ The address corresponding to Customer Number: _____

OR

☒ Firm or Individual Name SagaX Inc.

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number of CDs _____
☒ Specification *Number of Pages* 6
☐ Other (specify) _____
☒ Drawing(s) *Number of Sheets* 2

Application Size Fee: If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

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☐ Applicant claims small entity status. See 37 CFR 1.27.
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☐ No.
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SIGNATURE _____ Date May 22, 2005

TYPED or PRINTED NAME Gil Naor REGISTRATION NO. _____ *(if appropriate)*

TELEPHONE 972-54-5705061 Docket Number: _____

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First Named Inventor	GIL NAOR	Docket Number	

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Number 2 of 2

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Provisional Application

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Michael Ortenberg, Kfar Yona, Israel

PERMANENT CEREBRAL EMBOLIC PROTECTION

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to permanent cerebral embolic protection by a way of diverting the particulate originating in the heart and traveling in the blood flow to the Aorta, to the lower extremities.

Described are devices and methods for diverting emboli away from the carotid arteries in the aorta. The devices are aortic diverters that generally comprise a hollow tube with a substantially cylindrical, spherical or conical wall, which is impermeable to emboli and which has open ends that allow blood to enter one end, flow through the tube and exit the other end. Additionally, aortic diverters, which are planar rather than cylindrical are also shown. The methods of the invention generally include the steps of providing an aortic diverter carried by an intravascular catheter, introducing the intravascular catheter into the vascular system, advancing the intravascular catheter into the aortic arch and into the carotid arteries, and deploying the aortic diverter.

WHAT IS CLAIMED IS:

1. A method for protecting a patient against cerebral embolization wherein the diverter is secured to the lumen of one of the cerebral arteries branching from the aorta and is protruding to the aorta lumen:

(a) a first substantially tubular embodiment that is curved downstream of the aorta

(b) a second substantially spherical and which has an opening directed at the downstream of the aorta.

(c) a third substantially planner and which is secured in both the cerebral branch and in the descending aorta

2. The protection device of claim 1, wherein the whole embodiment is temporarily deformable to assume a delivery state in a reduced diameter size to allow delivery through a minimally invasive delivery system.

SUMMARY OF THE INVENTION

The present invention provides different embodiments for cerebral protection of emboli by diverting them from entering the cerebral braqnches to the lower extremities. The devices are anchored in the cerebral branches and have the effective filtering part protruding into the aorta lumen.

As the device is deployed within the cerebral branch vessel from the end of the catheter, it is designed to expand radially against the vessel's inner walls, and exert a certain amount of pressure in order to retain its positioning, even as the vessel may be prone to dilate elastically.
The amount of acceptable vessel dilation that may be accommodated is determined by the relative dimensions of the structure and vessel, the structure used and properties of the materials from which the structure is constructed.
As the device is further deployed, the filtering section unfolds into the aorta lumen in such a way as to divert any particles above a given size from entering the carotid branches. The device has an open end to allow for future interventions to take place and to not create a "jailed artery".

The structure may be fabricated in linear form from a single piece of material, by way of laser cutting or etching, avoiding joining mechanisms that may compromise the material properties. The structure may also be constructed from individual pieces (wires), and may or may not be accommodated by an additional filtering netlike mesh.
The structure is constructed from a material with (but not limited to) appropriate shape memory and/or superelastic properties.

Prior to deployment, the catheter end is positioned inside the vessel at a desired point for deployment. The structure is then deployed from the end of the catheter by suitable means, such that the portion which emerges unfolds gradually as it is no longer restrained by the catheter's walls. The folded

configuration of the structure within the catheter is configured such that, as the structure is deployed, it expands to press against the vessel's inner walls in the anchoring part, and regain its predetermined shape in the aorta lumen.
The folded structure is designed to fit a catheter of reasonable size to the application, and to be smooth sided in order to slide freely within the catheter through potentially tortuous paths and overcome the inevitable resistance caused by its affinity to expand.

Various forms of configurations may be used to allow the device to be collapsed inside a catheter. Three preferred configurations described herein below with reference to Figures 1-6.

The first substantially preferred embodiment (figure 1A-1B and 2A-2B) is a simple tube either straight or bended and which is open on both ends.

The second substantially preferred embodiment (figure 3A-3B) has a spherical shape in the aorta lumen and has an opening directed at the downstream of the aorta flow.

The third substantially preferred embodiment (figure 4A-4B) has an anchor in the carotid artery and an anchor in the descending aorta distal to the left carotid, and a linear section in between that acts as the filtering part.

Those skilled in the art will appreciate that the curvature of the device and the design of each section may be varied widely to serve the purposes of a given application Thus, according to the teachings of the present invention there is provided, a cerebral embolic protection device, the device comprising:
(a) a first substantially closed tubular section configured to assume a shape lying substantially on a virtual cylinder of given diameter which acts as the anchoring part; and (b) a second substantially tubular or spherical or linear section which acts as the filtering part.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

has a tubular shape (either straight or curved) anchored in the carotid and protruding into the aorta lumen, the anchoring section has a design which virtually applied enough radial pressure on the vessel wall as to avoid migration or tilting of the device, and the section which protrude into the aorta lumen is designed as a filter with a predetermined porosity. The tubes can be cut by laser from a tube of a specific dimensions

FIG. 1A is a schematic side view of a first preferred configuration of the Protective device, in which the filtering section is a partial cylindrical shape that is opened on one end to allow for blood to enter the carotid artery.
FIGS. 1B is a schematic side view of the embodiment of figure 1A implanted in the Innominate artery (by way of an example), protruding into the aorta.

FIG. 2A is a schematic side view of the first preferred configuration of the Protective device, in which the filtering section is curved towards the aorta downstream.
FIGS. 2B is a schematic side view of the embodiment of figure 2A implanted in the Innominate artery (by way of an example), protruding into the aorta.

FIG. 3A is a schematic side view of a yet another preferred configuration of the Protective device, in which the filtering section is spherical or "mushroom" shaped and has an open section on one end to allow for blood to enter the carotid artery.
FIGS. 3B is a schematic side view of the embodiment of figure 3A implanted in the Innominate artery (by way of an example), protruding into the aorta.

FIG. 4A is a schematic side view of a yet another preferred configuration of the Protective device, in which the filtering section is a planner in shape and is anchored at both ends by stent like sections at the carotid artery and the ascending aorta.
FIGS. 4B is a schematic side view of the embodiment of figure 4A implanted in the Innominate artery(by way of an example) and ascending aorta.

FIG. 5 is a schematic side view of yet another preferred configuration of the Protective device, in which the filtering section is a fully cylindrical in shape that is opened on one end to allow for blood to enter the carotid artery and is made of braided wires of differing diameters.

FIG. 6 is a schematic side view of the preferred configuration of figure 5 of the Protective device, in which the device is made of a platform of netlike structure and an additional net of a predetermine mesh.

Even within the individual implementations described herein, the devices of the present invention are believed to include numerous different aspects each of which is believed to be susceptible to patent protection individually. Thus, it should be appreciated that features of the invention indicated herein to be of particular importance should not necessarily be interpreted as necessary to all aspects of the invention, but rather according to the specific combinations of features as defined by the appended claims.

Drawings

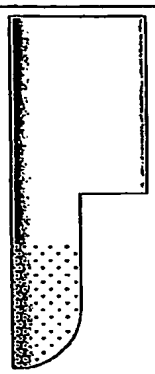

Figure 1A

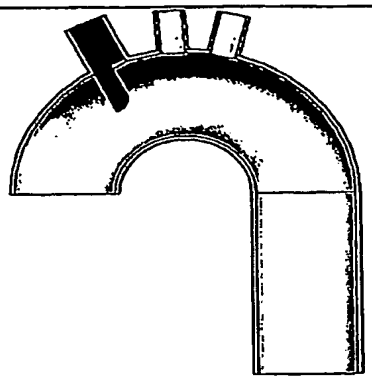

Figure 1B

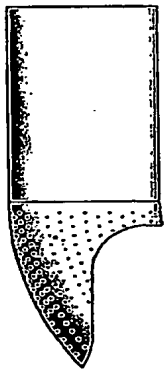

Figure 2A

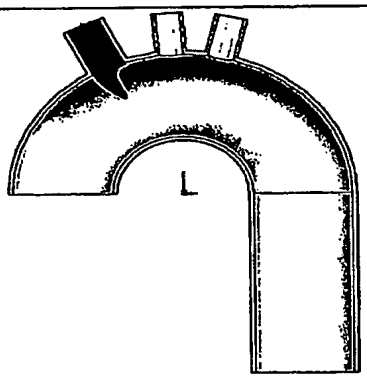

Figure 2B

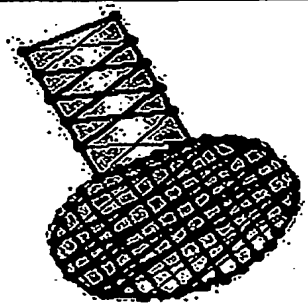

Figure 3A

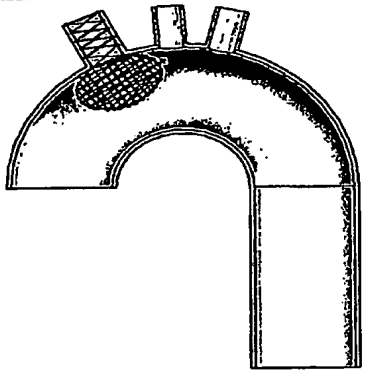

Figure 3B

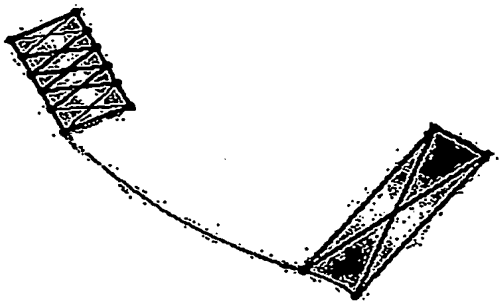

Figure 4A

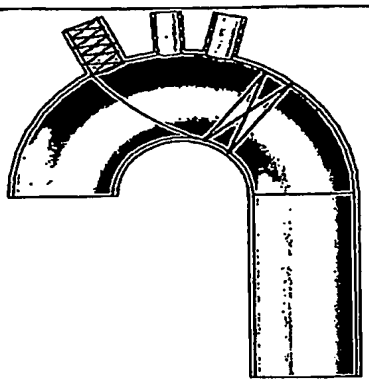

Figure 4B

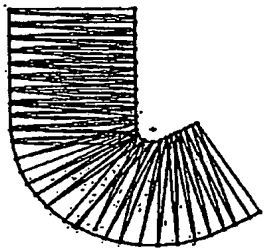

Figure 4A

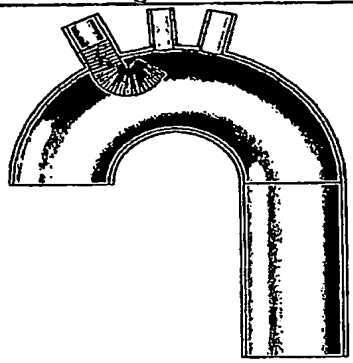

Figure 5B

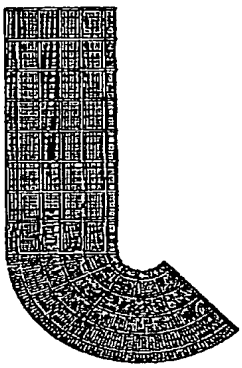

Figure 6A